Entry of the foregoing amendments is respectfully requested.

Respectfully submitted,
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Version with Markings to Show Changes Made

Claims 1 and 13 have been amended as follows:

1. (Amended) A method of administering recombinant adeno-associated virus (rAAV) virions to a human, comprising:

(a) providing at least one recombinant adeno-associated virus (rAAV) [rAAV] virion, said at least one rAAV virion comprising a vector further comprising a heterologous nucleic acid sequence, which sequence results in a therapeutic effect when delivered to said human; and

(b) delivering said rAAV virions to [a] said human under conditions wherein said heterologous nucleic acid sequence is expressed at a therapeutic level, wherein said human has preexisting anti-AAV antibodies[;

(c) wherein said heterologous nucleic acid sequence is expressed].

13. (Amended) A method of treating hemophilia in a human, comprising:

(b) providing at least one recombinant adeno-associated virus (rAAV) virion, said rAAV virion comprising a vector further comprising a heterologous nucleic acid sequence further comprising a gene encoding a blood coagulation factor; and

(b) delivering said rAAV virions to said human under conditions wherein said gene is expressed at a therapeutic level, wherein said human has preexisting anti AAV antibodies[; and

(c) wherein said blood coagulation factor is expressed at a level having a therapeutic effect].

Claim 3 has been canceled.

Currently Pending Claims

1. (Amended) A method of administering recombinant adeno-associated virus (rAAV) virions to a human, comprising:

(a) providing at least one rAAV virion, said at least one rAAV virion comprising a vector further comprising a heterologous nucleic acid sequence, which sequence results in a therapeutic effect when delivered to said human; and

(b) delivering said rAAV virions to said human under conditions wherein said heterologous nucleic acid sequence is expressed at a therapeutic level, wherein said human has preexisting anti-AAV antibodies.

2. The method of claim 1, wherein said preexisting anti-AAV antibodies are anti-AAV-2 antibodies.

4. The method of claim 1, wherein said heterologous nucleic acid sequence codes for a polypeptide.

5. The method of claim 4, wherein said polypeptide is Factor IX.

6. The method of claim 5, wherein said Factor IX is secreted into an extracellular space.

7. The method of claim 5, wherein said Factor IX is secreted into a blood vessel.

8. The method of claim 1, wherein the delivering of said rAAV virions to said human is by injection to a muscle.

9. The method of claim 8, wherein said injection is to one or more slow-twitch muscle fibers of said muscle.

10. The method of claim 8, wherein said injection is performed at least once on said muscle.

11. The method of claim 1, wherein the delivering of said rAAV virions to said human is by injecting into a duct of a secretory gland.

12. The method of claim 11, wherein the secretory gland is a liver.

13. (Amended) A method of treating hemophilia in a human, comprising:
(a) providing at least one recombinant adeno-associated virus (rAAV) virion, said rAAV virion comprising a vector further comprising a heterologous nucleic acid sequence further comprising a gene encoding a blood coagulation factor; and
(b) delivering said rAAV virions to said human under conditions wherein said gene is expressed at a therapeutic level, wherein said human has preexisting anti AAV antibodies.

14. The method of claim 13, wherein said preexisting anti-AAV antibodies are anti-AAV-2 antibodies.

15. The method of claim 13, wherein said blood coagulation factor is Factor IX.

16. The method of claim 15, wherein said Factor IX is human Factor IX.

17. The method of claim 15, wherein said Factor IX is secreted into an extracellular space.

18. The method of claim 15, wherein said Factor IX is secreted into a blood vessel.

19. The method of claim 17, wherein said Factor IX is human Factor IX.

20. The method of claim 18, wherein said Factor IX is human Factor IX.

21. The method of claim 13, wherein the delivering of said rAAV virion to said human is by injection to a muscle.

22. The method of claim 19, wherein said injection is to one or more slow-twitch muscle fibers.

23. The method of claim 20, wherein said injection is to one or more slow-twitch muscle fibers.

24. The method of claim 21, wherein said injection is performed at least once on said muscle.

25. The method of claim 22, wherein said injection is performed at least once on said muscle.

26. The method of claim 23, wherein said injection is performed at least once on said muscle.